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IN THE

Supreme Court of the United States

October Term, 1980

No. 80-2182

INWOOD LABORATORIES, INC. and
PREMO PHARMACEUTICAL LABORATORIES, INC.,
Petitioners,

against

IVES LABORATORIES, INC.
Respondent.

ON A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE AND BRIEF AMICI CURIAE OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS AND THE NATIONAL RETIRED TEACHERS ASSOCIATION IN SUPPORT OF THE PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE* IN SUPPORT OF THE PETITIONER AND STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Association of Retired Persons (AARP) and the National Retired Teachers Association (NRTA), of 1909 K Street, N.W., Washington, D. C. 20049, respectively move the Court pursuant to Rule 36 of the Rules of the United States Supreme Court for permission to file the attached brief *amici curiae* on a Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit. The grounds for this motion, which grounds also disclose the interest of the *amici,* are set forth below.

AARP and NRTA are affiliated and jointly administered not-for-profit membership corporations of more than 12,500,000 persons over the age of 55. This figure represents approximately one out of four people over the age of

55 nationwide, the largest organized group of older Americans in the country. Among the purposes of AARP are: to enhance the quality of life for older persons; to promote independence, dignity and purpose for older persons; to lead in determining the role and place of older persons in society; and to improve the image of aging. Among the purposes of NRTA are: to promote the social welfare and needs of retired teachers, administrators, and all other persons eligible for membership, to improve the quality of life for retired teachers, school administrators, and all older Americans, to the end that aging is achieved with independence, dignity and purpose; and to sponsor research on physical, psychological, social, economic, and other aspects of aging.

Inwood Laboratories, Inc. and Premo Pharmaceutical Laboratories, Inc.,[1] manufacturers of the generic drug cyclandelate, filed their Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit seeking reversal of the holding that the generic manufacturers were liable for contributory trademark infringement by virtue of their packaging of cyclandelate in the same color capsule as used by respondent, in conjunction with their employment of truthful comparative advertising. The questions presented by the Petition are: (1) whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement; and (2) whether Section 32 of the Lanham Act, 15 U.S.C. §1114, grants a trademark owner monopoly rights in the color of its product.

The opinion of the Court below answering both questions in the affirmative seriously impinges upon the interests of the elderly.

The generic drug industry provides vital service to the elderly: it offers generic equivalents such as cyclandelate as alternatives to the higher priced brand-name drugs. It

1. Hereinafter referred to as the "generic manufacturers."

promotes competition in the pharmaceutical marketplace, with the resultant effect of cost containment. The decision of the Second Circuit places into serious question the future competitive capacity of the generic drug industry.

The color in which drugs are packaged involves far more than aesthetics; it is a vital competitive characteristic. During the period in which their patent is in effect, brand-name companies establish a color which identifies a particular drug in the eyes of dispensers, *i.e.* physicians, hospitals, and pharmacists, as well as in those of the patient. The introduction of a generic equivalent dressed in a different color will be met with substantial resistance, by reason of which the generic competitor will be foreclosed from a substantial pocket of the market.

Thus, the result of the Second Circuit's decision, severely restricting the ability of generic manufacturers to dress their drugs in the "accepted" colors used by the brand-name producers, will stifle competition and prices will inevitably rise. This threat to the continued availability of lower-priced, bioequivalent generic drugs, and the downward pressure on prices created by their competition with brand-name drugs, seriously prejudice older persons, a category of Americans with expanded need for the drugs, but with often limited means to pay for them.

As retired persons, many members of AARP and NRTA live on relatively fixed incomes and, because of their advanced age, many also depend on regular or frequent administration of pharmaceuticals for their continued well being. Because of the need to contain the already high, and rapidly increasing, cost of health care, including expenses for drugs, this case is especially critical to the health and welfare of AARP and NRTA members and of all older Americans.

The elderly spend a far greater amount *per capita* on health care each year than younger persons. In 1979, the average annual health care expenditure for persons over 65

was $2,257 or 3½ times the average amount expended by persons under 65. While older Americans comprise only 11.2% of the population, they spend 29% of the total nationwide expenditure for personal health care.[2] With respect to drug costs, all Americans expended $15,098,000,000 for drugs and drug sundries in the calendar year 1978.[3] Of this figure, $3,331,000,000 or 22% of the nationwide total was spent by persons 65 years of age and older.[4] On a *per capita* basis, older persons' drug costs are nearly twice as much as those of younger persons.[5]

Older Americans pay for the overwhelming majority of these costs out of their own pocket. Medicare provides no reimbursement for prescription drugs. Medicaid is only available for the poor, and indeed only provides benefits for approximately 50% of the poor. Consequently, only 15.6% of drug costs to the elderly are covered by the combination of Medicare and Medicaid and other types of public assistance.[6] Thus the elderly must privately finance a full 84.4% of these drug costs, largely out of their fixed, and increasingly inadequate, incomes.

Since the over 12.5 million members of the amici are directly and severely affected by the cost of drugs, and because the decision of the Second Circuit endangers the continued viability of the generic drug alternative, amici have a vital interest in the ultimate question presented: whether Section 32 of the Lanham Act grants a trademark owner a monopoly over the color of its product.

The amici have been unable to obtain the consent of the respondent to the filing of the attached brief, thus necessitating this motion.

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2. Gibson, *National Health Expenditures*, 1979, 2 HEALTH CARE FINANCING REVIEW 1 (Summer 1980); Fisher, *Differences by Age Groups In Health Care Spending*, 1 HEALTH CARE FINANCING REVIEW 4 (Spring 1980).

3. Fisher, *Differences By Age Groups in Health Care Spending*, 1 HEALTH CARE FINANCING REVIEW, 4 at 81 (Spring, 1980).

4. *Id.*

5. *Id.*

6. *Id.* at *89.*

WHEREFORE, AARP and NRTA respectfully move for permission to file the attached brief amici curiae in support of the Petition for a Writ of Certiorari in this matter.

Respectfully submitted,

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BRIEF AMICI CURIAE IN SUPPORT OF THE PETITIONER

INTRODUCTION

The overriding interest of AARP and NRTA in the health care field is to foster and promote efficient delivery to the elderly of the best possible services at the least possible cost, thus making them readily available even to persons living within fixed and limited incomes. Amici steadfastly maintain that elimination of all anti-competitive barriers in the drug industry is essential to the achievement of this ultimate goal.

Brand name manufacturers develop an overwhelming head-start in the market for a particular drug, Cyclospasmo being a prime example. By virtue of their patent, they enjoy a seventeen year product monopoly, and direct an exhaustive advertising campaign towards physicians. As a consequence, most physicians identify the drug with its brand name and write prescriptions accordingly.

In recognition of the vast competitive superiority thus obtained by brand-name manufacturers, the legislatures of 48 states have adopted so-called "generic drug substitution" statutes which either require or allow the dispensing pharmacist to substitute a generic drug, unless the physician otherwise directs. These statutes are evidence of the pervasive local interest in fostering effective competition in the pharmaceutical market in order to achieve some measure of cost containment.

Instead of accommodating this social interest, the Second Circuit has ignored it, and indeed done it considerable violence, by effectively granting brand-name producers a monopoly over the color in which their drug is produced. These colors perform several functions with regard to health, drug identification and patient compliance such that denial of their use to generic manufacturers, who come into the marketplace long after the brand-name drug has secured a strong foot-hold, puts them at a severe competitive disadvantage. And any threat to the economic viability of the generic drug industry, carries with it a concommitant threat to the cost containment achieved by their competitive presence. The consequence of the Second Circuit's decision will be to provide brand-name drug manufacturers with an untoward competitive advantage, largely at the expense of older Americans.

ARGUMENT

Amici respectfully join in the legal argument advanced by the Petitioners. We respectfully highlight below several points of direct concern to AARP and NRTA.

POINT I

THE SECOND CIRCUIT'S DECISION GRANTS BRAND-NAME DRUG MANUFACTURERS A DECIDED MARKETING ADVANTAGE BY VIRTUE OF THE FUNCTIONALITY OF DRUG COLOR AND THUS THREATENS THE CONTINUED COMPETITIVE CAPACITY OF GENERIC DRUG MANUFACTURERS

The colors used in drug packaging are functional in various ways, particularly as regards the elderly. As expressly found by the District Court,[1] many patients, especially elderly patients, associate the color of a drug with its therapeutic effect. Since the brand-name product, in the color of the capsule containing it, is the exclusive source of a drug while it is under patent, a drug will be identified as "my little blue heart pill." When a bioequivalent generic drug becomes available, but in a different color, there is considerable distrust with respect to the generic alternative. This distrust may lead to lack of patient compliance in a state, such as New York, which has adopted a mandatory generic drug substitution statute. When faced with patient resistance to drugs packaged in an unfamilar color, physicians will prescribe the brand-name drug to insure that reluctant patients will take it. Indeed, problems with patient compliance may convince physicians to insist as a matter of policy that pharmacists fill prescriptions with brand-name drugs, thereby denying all his patients access to lower-priced generics.

Second, even if patients eventually accept variations in color, they do so only after considerable anxiety and confusion. This can often result in the patient being deprived of the so-called "placebo effect" experienced by many patients, *i.e.* the psychological healing power caused by the confidence and assurance of a patient taking medication that he has been advised would help him.

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1. *See* Appendix C to the Petition, p. 63a

Third, many elderly patients who take multiple medications identify each drug by its color. Color variations in the same medicine would upset the identification procedures employed by elderly patients, and create widespread confusion.

Fourth, the potential for confusion has lead hospitals, pharmacies and wholesalers to refuse to purchase generic drugs colored differently than the brand-name drugs.

Fifth, uniform drug coloring can save lives, as it can serve to identify drug overdoses for physicians and emergency personnel acting in life-threatening situations.

In light of the functionality of drug color, the District Court found, as a matter of fact, that "to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage."[2] The District Court further found that "color is an important ingredient in the commercial success of the product."[3]

Labeling these functionality aspects to the issue "unconvincing,"[4] the Second Circuit held that the generic manufacturers' imitation of the color in which respondent packaged its Cyclospasmol constituted "contributory trademark infringement" violative of Section 32 of the Lanham Act. The Court of Appeals reasoned that the generic manufacturers should have reasonably anticipated that some druggists might intentionally or accidentally apply respondent's trademark to cyclandelate.[5] Because this possibility will always exist, the Court of Appeals has effectively granted a monopoly over color to brand-name drug manufacturers, and given them a decided advantage over generic competitors who must sell the generic drug in a far less marketable color. Consequently, the Second Circuit, in a

2. *Id.* at 63a.
3. *Id.*
4. *See* Appendix D to the Petition, p. 85a.
5. *See Id.* at 82 a-83a.

radical departure from settled law,[6] has granted proprietary rights in color in the absence of "secondary meaning" and despite evidence of functionality, and has sharply contradicted the federal policy, as enunciated by this Court, favoring the exact copying of unpatented merchandise.[7] In so doing, it seems to have foresaken the interest of the public in general, and that of the elderly in particular, in favor of the profit interest of the drug manufacturers.

To the extent that generic manufacturers cannot compete with the brand-name producers in light of the color monopoly granted by the Court of Appeals in this case, and thus are forced out of the market, the brand-name manufacturers will then enjoy restoration of their product monopoly which had expired along with their patent. This would remove any hope for cost containment in the pharmaceutical industry.

To the extent that generic manufacturers manage to remain in the market, drug identification by color will no longer be possible, because of the inevitable claim of trademark infringement. Furthermore, patients or physicians whose confidence depends upon the functionality of drug color must suffer the higher price commanded by the brand-name companies. These functional aspects principally affect the elderly, and thus will be mainly paid for by a group of Americans least able to afford it.

CONCLUSION

Amici have a special interest and concern in expanding the competitive forces at work in the pharmaceutical market. Granting brand-name producers a monopoly over product color in light of its functional nature, will seriously limit or eliminate these competitive forces, will preclude

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6. *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Upjohn Co. V Schwartz*, 246 F.2d 254 (2d Cir. 1957).

7. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964); *Compro Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 238 (1964).

drug identification through uniform coloring, and will reserve the functional benefits of drug color to those willing and able to pay higher prices for it.

WHEREFORE, amici respectfully request that the Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit be granted.

Respectfully submitted,

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